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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/908,453	08/07/1997	GARY RUVKUN	08472/704002	9530

7590 03/26/2002
CLARK & ELBING
176 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/26/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/908,453

Applicant(s)

RUVKUN ET AL.

Examiner

Ram Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-16 and 18-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 14 and 21-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 10-13, 15, 16, 18-20, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

DETAILED ACTION

1. The amendment and response filed 1-7-02 has been entered.
2. The supplemental reply filed 3-18-02 has been entered.
3. Amendments to claims 12, 15, 16 and 29 30 have been entered.
4. Claims 1-4, 14, and 21-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 15.
5. This application contains claims 1-4, 14, and 21-28 drawn to an invention nonelected with traverse in Paper No. 15. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
6. Claims 8, 10-13, 15, 16, 18-20, 29, and 30 are instantly under consideration in the instant application.

Claim Rejections - 35 U.S.C. ' 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 8, 10-13, 16, 18-20, 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated and purified DNA molecule, wherein said DNA encodes the AGE-1 polypeptide of SEQ ID NO: 1, a vector comprising the DNA molecule, a recombinant host cell comprising the vector, a method of producing the AGE-1 polypeptide by culturing the recombinant host cell and isolating the AGE-1 polypeptide, and a method of identifying an AGE-1 modulatory compound that is capable of decreasing PI 3-kinase activity of the AGE-1 polypeptide does not reasonably provide enablement

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for other embodiments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is noted that the total enablement rejection of claims 8, 10-13, 16, 18-20, 29, and 30 has been modified to a scope rejection in view of the applicants' arguments, declaration by the inventor and the articles provided in the supplementary response. However, the rejection pertaining to a DNA that encodes an AGE-1 protein that has 95% amino acid sequence identity to SEQ ID NO 1, claims 29 and 30, any AGE-1 from any animal, and other issues is maintained for reasons of record set forth in the previous office actions of 8-17-99, 5-4-00, 6-7-01.

Response to Applicant's Arguments:

It is noted that applicants have only discussed the issue as to whether AGE-1 is a PI 3-kinase. Since, the rejection pertaining to this issue has been withdrawn, applicants argument are moot.

9. Claims 15 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons set forth in the previous office actions of 8-17-99, 5-4-00, and 6-7-01, discussions therein and as discussed below.

It is noted that after the amendment to claim 15, while an artisan may not require the sequence of the AGE-1 promoter, still for practicing the claimed method, since the compound would decrease the transcription of the AGE-1 gene, an artisan would require the information as to how to determine that the transcription of AGE-1 gene has been altered and not that of any other gene. The In other words, an artisan would have to use proper negative and positive controls

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for practicing the claimed method, however, the specification does not teach what these controls are and the art does not teach any controls. The specification does not teach as to how a compound will be selected for use in the instantly claimed invention.

Response to Applicant's Arguments:

It is noted that the applicants have not presented any arguments regarding the enablement issues.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 12, 15, 16, 18-20 and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite because it is unclear as to what is meant by step (c) which recites the phrase "measuring AGE-1 gene expression in said nematode cell, a decrease in AGE-1 gene expression in said nematode cell following contact with said candidate compound, related to AGE-1 gene expression in an untreated nematode cell"?

Claim 15 recites the limitation "the endogenous AGE-1 DNA of claim 8" in step (a). There is insufficient antecedent basis for this limitation in the claim because claim 8 does not recite the term "an endogenous AGE-1 DNA".

Claim 16 is indefinite because it is unclear as to what is meant by the phrase "measuring the PI 3-kinase activity of said cell, a decrease in AGE-1 PI 3-kinase activity of said cell following contact with the candidate compound, relative to AGE-1 PI 3- kinase activity in an untreated cell"?

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12. No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instructions, Applicants are referred to <http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (703) 305-3388.

Ram R. Shukla, Ph.D.


DAVE T. NGUYEN
PRIMARY EXAMINER